

Docket No.: 5156-0103PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tomas J. EKSTRÖM et al.

Application No.: 10/588,379

Confirmation No.: 8424

Filed: August 2, 2006

Art Unit: N/A

For: COMPOUNDS FOR ENHANCED CANCER
THERAPY

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL
REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE
1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☒ a. Copies of cited U.S. patents and patent application publications are not included.
Copies of foreign patent documents and non-patent literature are included.

☒ b. Enclosed herewith are copies of the eleven (11) documents that were cited in the International Search Report (PTO/SB/08 Form, Cite Nos. CA-CK). Also enclosed are copies of other relevant citations.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

PCT/EP2005/050805 filed February 25, 2005

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☐ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☒ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.
(This section is not to be used with RCE's.)

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. **Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.


☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 02-2448, under Order No. 5156-0103PUS1 from which the undersigned is authorized to draw. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

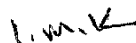
Dated: November 2, 2006

Respectfully submitted,

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Attachment(s):

- ☒ PTO-SB08
☒ Documents
☐ Foreign Search Report
☐ Fee
☐ Other:



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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/588,379
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				First Named Inventor	Tomas J. EKSTRÖM
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	5156-0103PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-5,939,455	08-17-1999	REPHAEL	
	AB*	US-5,605,930	02-25-1997	SAMID	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	WO-03/017763	03-06-2003			
	BB	WO-03/084611	10-16-2003			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	ASKLUND THOMAS ET AL: "Gap junction-mediated bystander effect in primary cultures of human malignant gliomas with recombinant expression of the HSVtk gene." EXPERIMENTAL CELL RESEARCH, vol. 284, no. 2, 1 April 2003 (2003-04-01), pages 185-195, XP002377912 ISSN: 0014-4827 page 191-194, paragraph entitled "Discussion"; figure 6.	
	CB	ALMQVIST P M ET AL; "DIFFERENTIATION OF HUMAN PRIMARY GLIOBLASTOMA CELLS BY A PHENYLBUTYRATE," SOCIETY FOR NEUROSCIENCE ABSTRACT VIEWER AND ITINERARY PLANNER, vol. 2002, 2002, pages Abstract No. 802.8; URL- http://sf.XP009065441 & 32ND ANNUAL MEETING OF THE SOCIETY FOR NEUROSCIENCE: ORLANDO, FLORIDA, USA; NOVEMBER 02-07, 2002. Abstract.	
	CC	ALTENBURG B C ET AL: "MODIFICATION OF THE PHENOTYPE OF MURINE SARCOMA VIRUS TRANSFORMED CELLS BY SODIUM BUTYRATE EFFECTS OF MORPHOLOGY AND CYTOSKELETAL ELEMENTS" EXPERIMENTAL CELL RESEARCH, vol. 102, no. 2, 1976, pages 223-231, XP009065490 ISSN: 0014-4827, page 228-231, paragraph entitled "Discussion".	
	CD	JIAN WEIGUO ET AL: "Combination of adenovirus mediated suicide gene therapy with the histone deacetylase inhibitors butyrate, phenylbutyrate and electroporation in bladder cancer in vitro and in vivo." PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH ANNUAL MEETING, vol. 44, July 2003 (2003-07), pages 1300-1301, XP001247005 & 94th ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH; WASHINGTON, DC, USA; JULY 11-14, 2003 ISSN: 0197-016X. Abstract.	

Examiner Signature		Date Considered	
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CP	YOSHIDA ET AL: "Clinical gene therapy for brain tumors, Liposomal delivery of anticancer molecule to glioma," Jour Neuro-Oncology, 65, pp. 261-267.	

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	CQ	BERG ET AL: "Pharmacokinetics and cerebrospinal fluid penetration of phenylacetate and phenylbutyrate in the nonhuman primate," Cancer, Chemotherapy and Pharmacology, pp. 1-11.	
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	CX	BARTOLI ET AL: "Effect of trichostatin a and 5'-azacytidine on transgene reactivation in U937 transduced cells," Pharmacol Res., 48(1):111-8.	
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	CD1	GERMANO ET AL: "Adenovirus/herpes simplex-thymidine kinase/ganciclovir complex: preliminary results of a phase 1 trial in patients with recurrent malignant gliomas," Journal of Neuro-Oncology, 65, pp. 279-289.	
	CE1	GEROLAMI ET AL: "Herpes simplex virus thymidine kinase-mediated suicide gene therapy for hepatocellular carcinoma using HIV-1-derived lentiviral vectors," Journal of Hepatology, 40, pp. 291-297.	
	CF1	BARNES ET AL: "Current strategies in gene therapy for ovarian cancer," Current Opinion in Obstetrics and Gynecology, pp. 47-51.	
	CG1	KUBO ET AL: "Phase 1 dose escalation clinical trial of adenovirus vector carrying osteocalcin promoter-driven herpes simplex virus thymidine kinase in localized and metastatic hormone-refractory prostate cancer," Human Gene Therapy, 14, pp. 227-241.	

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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CH1	PULKKANEN ET AL: "The combination of HSV-tk and endostatin gene therapy eradicates orthotopic human renal cell carcinomas in nude mice," Cancer Gene therapy, 9, pp. 908-916.
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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1. MJK